PATENT SPECIFICATION

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DRAWINGS ATTACHED

1 265 246

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(54) SURGICAL VASCULAR PROSTHESIS

(71) I, SIGMUND ADAM WESOLOWSKI, a citizen of the United States of America, residing at 44 Roosevelt Avenue, East Rockaway, New York, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to prosthesis constructed to maintain an open lumen when placed in an animal body, particularly in the human body. More particularly, this invention relates to vascular implants for surgical use in the repair and replacement of vessels and tracts in human and animal bodies.

During the past decade, considerable attention has been given to the development of artificial vascular parts or grafts as implants for animal bodies. Synthetic fibers such as VINYON-N, NYLON, ORLON, DACRON, TEFLON, and IVALON have been woven and knitted into tubes and other suitable shapes, for use as arteries, veins, ducts, esophagi and the like. ("ORLON", "DACRON" and "TEFLON" are Registered Trade Marks.)

It has been recognized that an artificial graft must meet a number of standards in order to be of value. In particular, the graft must have certain physical properties such that it can be readily handled and manipulated during the specific surgery calling for its use. It must be flexible, for such is essential during an operation when time is critical and the graft must be accommodated to the artery, vein or the like to which it is being secured. It is sometimes necessary in surgery to bend a device or graft either around or under a body organ. An essential feature is that the graft be sufficiently rigid, though bendable, to allow for flexing without collapse and closing of the lumen thereof. If the graft does not have such strength, there is ever present the danger that when bent or flexed acutely in the body the lumen would collapse, leading to fatality.

It has also been recognized that a suitable prosthesis for the body should be non-toxic, flexible and porous. The ideal prosthesis should retain its strength permanently in intimate contact with the body fluids and should be readily acceptable and incorporated into the tissues. Porosity is an important characteristic of such a prosthesis to avoid the formation of fluid pockets and to promote the growth through the fabric of repair tissue. Proper merging of the fabric with the body structure is also essential.

According to the invention there is provided a polyester fiber paper vascular prosthesis characterized by a porosity of from 550 cc. to 8,000 cc. per minute per square centimetere and having a wall thickness of from about 64 microns to about 254 microns.

The prosthesis may comprise an association of short polyester fibers of indefinite length that can be handled on conventional paper-making machinery, said fibers ranging from 10 to 15 microns in diameter. The fibers may be randomly arranged and bonded together to form a non-woven, paper-like sheet. The structure may be stabilized by fusion of some of the polyester fibers to cause adhesion. Alternatively, various adhesives may be used for this purpose, i.e., a polyamide resin produced by the condensation of a polycarboxylic acid with polyamide (VERSAMID). ("VERSAMID" is a Registered Trade Mark). If an adhesive is used, it must be applied sparingly to "spot-weld" the polyester fibers at spaced intervals through the area of the paper sheet so as not to decrease unduly the porosity of the fabric. When a a polyamide resin is employed as an adhesive, it is heat-cured to polymerize and "set" the adhesive.

The prosthesis may be in the form of a gossamer tube of high porosity. The prosthesis may be used to form an artificial vascular part for an animal body and is

suitable for use as a replacement for a damaged artery.

In order that the invention may be more readily understood, reference will now be made to the accompanying drawings in which:

Figure 1 is a perspective view of a DACRON paper tube embodying the invention;

Figure 2 is a perspective view of a DACRON paper vascular implant of bifurcated form;

Figure 3 is a cross-section of a vascular prosthesis on the Line 3—3 of Fig. 1;

Figure 4 is a longitudinal cross-section on the Line 4—4 of Fig. 1; and

Figure 5 is a cross-section of the tube shown in Figs. 1 and 4 when in a crimped condition.

The paper that is used to construct the prosthesis of the present invention may consist essentially of polyester (polyethylene terephthalate) fibers of indefinite length. The paper is desirably between about 64 microns and 254 microns in thickness. To obtain bonding of the individual fibers throughout the paper sheet, there may be included in the polyester fiber composition a small amount (1—4%) of a polyester fiber having a melting point that is substantially below the melting point of the polyester fibers that constitute the major portion of the paper composition. To obtain bonding, the paper sheet, after formation, is heated for a short period of time to the fusion temperature of the low melting polyester fibers, but below the fusion temperature of the higher melting polyester fibers, and then cooled to room temperature.

The vascular prostheses of the present invention may be constructed, as best shown in Fig. 1, by rolling an oblong sheet to form a tube 10 and cementing the longitudinal seam 11 with a suitable adhesive. Adhesives that may be used for this purpose are the 2-cyanoacrylic esters such as methyl 2-cyanoacrylate and isobutyl 2-cyanoacrylate. Alternatively, the longitudinal seams may be secured by sewing with a polyester fiber thread, or by heat sealing.

Bifurcated structures of the type shown in Fig. 2 may be manufactured by making a small longitudinal cut 12 in the wall of a tube and joining thereto one end of a second tube 13 with an appropriate adhesive or by sewing, or heat sealing.

The tubes of the present invention may be crimped to allow for flexing and bending without collapse and closing of the lumen, by placing the uncrimped tube on a glass mandrel of slightly smaller diameter and compressing the tube longitudinally. The glass mandrel with the compressed tube theron is then "heat-set" at a temperature slightly below the fusion temperature of the polyester fibers that are present in the paper, and permitted to cool to room temperature. After cooling, the crimped prosthesis having the structure illustrated in Fig. 5 may be removed from the mandrel.

Paper polyester fiber tubes constructed in accordance with the present invention exhibit excellent mechanical and physical properties and may be sutured quite like normal aorta. Tests have been performed by implantation into the thoracic aorta of growing pigs for periods of six months. The prostheses demonstrate in general excellent healing properties that compare well with the best healing prosthesis of knotted and woven fabrications and show no incidence of obstruction that may sometimes result from the secondary deposition of thrombus upon the inner surface. The general observations with respect to the ultimate fate, i.e. the fibrotic and cellular reaction, stenosis, and obstruction of various prostheses when used as arterial replacements in pigs is summarized in the following table. (See Table I.)

In the Table, the term "thickness of inner capsule" refers to the thickness of the layer of fibrous tissue formed within the respective prosthesis, and the term "percentile residual lumen" refers to the cross-sectional area of the unobstructed passage or lumen of the respective prosthesis expressed as a percentage of the total cross-sectional area of the prosthesis. For a fuller understanding of these terms, reference should be made to "The Evaluation of Tissue and Prosthetic Vascular Grafts" by Sigmund A. Wesolowski M.D., published (1962) by Charles C. Thomas, Springfield, Illinois, U.S.A.

It appears to be an advantage of the polyester fiber paper tubes that the inner capsule is thinner than previously experienced with other prostheses that have been used.

As indicated above, the articles formed as described herein are useful as tubular grafts. They have desired characteristics as revealed by their manouverability and flexing quality and capability of maintaining an open lumen when flexed. In addition, they have the desired feature of porosity as well as integrating well with body tissue.

TABLE I

RELATIVE ACCEPTABILITY OF DACRON PAPER VASCULAR PROSTHESES

Fabrication	Water Porosity*	Wall Thickness (Microns)	Average Fate in Growing Pig		
			(mm) Thickness of Inner Capsule	Calcification Index*	Percentile Residual Lumen
DACRON, knit, (Wesolowski 40 needle)	4,000	279	0.9	21	66
DACRON, weave, stretch	3,820	430	1.0	35	62
DACRON PAPER TUBE	8,000	64	0.7	39	53**
DACRON, knit, (Pilling, 1957)	1,600	590	0.9	162	66
DACRON, knit, (U.S.C., 1960)	2,500	508	1.1	300	65
DACRON, knit, (U.S.C., 1962)	2,700	456	1.4	220	37

*Wesolowski scale.

**If corrected for external construction, percentile residual lumen > 70

WHAT WE CLAIM IS:—

1. A polyester fiber paper vascular prosthesis characterized by a porosity of from 550 cc. to 8,000 cc. per minute per square centimeter and having a wall thickness of from about 64 microns to about 254 microns.

2. A vascular prosthesis as claimed in

Claim 1, wherein the porosity is 8,000 cc. per minute per square centimeter and the wall thickness is 64 microns.

3. A vascular prosthesis as claimed in Claim 1 or Claim 2, in crimped form.

4. A surgical vascular prosthesis substantially as hereinbefore described with reference to Figures 1, 3 and 4, or Figure 2, or Figure 5 of the accompanying drawings.

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1265246 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

FIG.1.

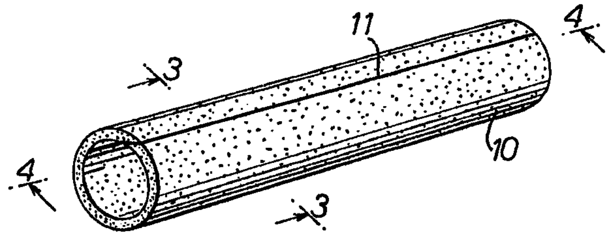

FIG.2.

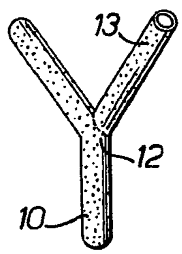

FIG.3.

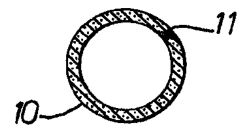

FIG.4.

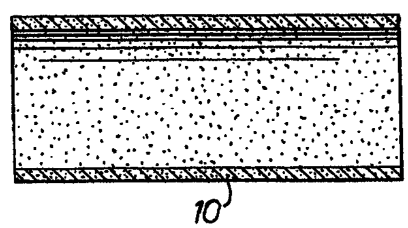

FIG.5.